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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,561

10/04/2006

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20350 7590 03/18/2009  
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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/554,561	<b>Applicant(s)</b> EBINA ET AL.	
	<b>Examiner</b> CHERIE M. WOODWARD	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/06, 2/15/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group III (claims 4-6) in the reply filed on 12/29/2008 is acknowledged.
2. Claims 1-3 and 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/29/2008.

### *Information Disclosure Statement*

3. The information disclosure statement (IDS) submitted on 6/8/2006 and 2/15/2008 have been considered by the examiner. The examiner reviewed the cited Japanese publications on the Patent Abstracts of Japan website using the English language machine translation provided on the PAJ website. The examiner also corrected the first author name of the Rosenzweig publication and added the date of publication, which was omitted by Applicant. A copy of the Kanezaki et al., reference is also provided herein, as no copy of the reference was provided by Applicant.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kanezaki, et al., (Biochem Biophys Res Commun. 26 Sept 2003;309:572-577).

Kanezaki et al., teach the detection of the human insulin receptor alpha subunit in blood that functions to inhibit insulin activity by binding with plasma insulin, thereby increasing blood glucose levels (abstract; Figure 6, p. 577, column 1, second paragraph). The correlation of the interaction of a free human insulin receptor alpha subunit and the onset of type 2 diabetes is taught at p. 572, column 2, lines 14-15 (compare instant claims 4 and 5). Immunoprecipitation with anti-insulin receptor alpha monoclonal antibodies are taught in Figure 3 (compare instant claim 6).

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It is noted that the Kanezaki et al., reference was published before the filing of the PCT application (of which the instant case is a national-stage entry under 35 USC 371) and before priority document application JP 2003-121955, but after priority document application JP 2003-433303. Although Japanese language certified copies of the priority documents were provided by Applicant, there were no accompanying English language translations and the examiner could not locate published applications on the Patent Abstracts of Japan website (which has machine translations of documents available electronically) in order to determine whether the JP 2003-433303 priority document is sufficient to antedate the teachings of the Kanezaki et al., reference. The examiner requires an English language translation of the priority documents in order to determine whether the instant rejection may be overcome by the JP 2003-433303 priority document.

### *Conclusion*

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - a. Rosenzweig et al., (J Biol Chem. 15 Oct 1990;265(29):18030-10834) teach detection of insulin receptor alpha subunits in retinal tissue, but do not teach detection of "free" insulin receptor alpha-subunits, as defined in the instant specification at p. 7, line 32.
  - b. Seedorf, et al., (US Patent 5,719,022, 17 February 1998) teaches that insulin receptor Type B alpha subunits have a 12 amino acid insertion at the C-terminal. The '022 patent teaches measurement of insulin receptor Type A and B cDNA by PCR, but does not specifically teach the measurement of free alpha-subunits or diagnosis of diabetes.
  - c. Song et al. (J. Immunol. 1985 Nov;135(5):3354-9) (previously cited of record) teaches antibodies to the alpha subunit of the insulin receptor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Primary Examiner, Art Unit 1647